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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,959	03/03/2004	Hal H. Katz	END-5011USNP	5088
27777	7590	08/09/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			KOHARSKI, CHRISTOPHER	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/791,959	KATZ ET AL.
	Examiner	Art Unit
	Christopher D. Koharski	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 June 2006.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
  - 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16-22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

Examiner acknowledges the amended claims 16 and 17 and withdrawn claims 1-15, currently claims 16-22 are pending for examination.

***Information Disclosure Statement***

No information disclosure statement (IDS) was submitted and there is not in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is not considering any information disclosure statement.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 16, 17, 18, 20, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Hickle et al. (US2003/0135087). Regarding claim 16, Hickle et al.

discloses a micro-processor based system that uses at least one sensor to monitor physiological patient parameters and starts a patient record and also stores historical data with at least a second connection element to the micro-processor (Figure 1, Page 2 [0011]).

Regarding claim 17, Hickle et al. further discloses a drug cassette system for delivering medication to the patent (Page 4, [0061]).

Regarding claim 18, Hickle et al. discloses the monitoring physiological conditions and disconnecting input signals and terminating a patient cases to start a new one (Page 17, [0162]).

Regarding claim 20, Hickle et al. discloses the step of querying the patient for consciousness (Figure 17).

Regarding claim 22, Hickle et al. discloses the step of priming an IV tube with a drug volume that is considered during the dose administration process (Page 14, [0135]).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C 103(a) as being unpatentable over Hickle et al. in view of Hickle (6,807,965). Hickle et al. meets the claim limitations as described above but does not include the step of delivering oxygen.

However, Hickle teaches a sedation device that dispenses oxygen. The reference teaches an apparatus that provides oxygen to the patient (Figure 7A).

At the time of the invention, it would have been obvious to use method of Hickle et al. with apparatus of Hickle to dispense oxygen. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Additionally, Hickle provides the motivation that that oxygen is used as a delivery agent for sedation. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hickle stating the use of oxygen as a treating medium.

Claim 21 is rejected under 35 U.S.C 103(a) as being unpatentable over Hickle et al. in view of Hickle (6,807,965). Hickle et al. meets the claim limitations as described above but does not include the step of a patient activating a response device.

However, Hickle teaches a patient response device that can be used. The reference teaches an apparatus that allows user input (col 21, ln 8-14, and element 226)).

At the time of the invention, it would have been obvious to use input device with Hickle et al. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Additionally, Hickle provides the motivation that the handheld device allows the patient to actively respond to the user. Therefore, one skilled in the

art would have combined the teachings in the references in light of the disclosure of Hickle stating the use of a handheld patient input device.

***Response to Arguments***

Applicant's arguments filed 6/20/2006 have been fully considered but they are not persuasive. Applicant's arguments regarding claims 16-18, 20 and 22 stating that Hickle et al. does not teach or suggest a micro-processor based patient unit having at least one second connection point to a micro-processor based procedure unit. Hickle et al. shows several processor-based units (8,7,4, and 1), the elements are processor controller units and are the patient based unit, controller, user interface, and drug delivery device. Connection elements are present between all of these elements are capable of meeting applicants claims (Figure 1).

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 7/28/2008

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